WHO TO CONTACT

Department of Energy Headquarters
Human Subjects Research Program
Office of Biological & Environmental Research
Phone: 301-903-3213
E-mail: humansubjects@science.doe.gov

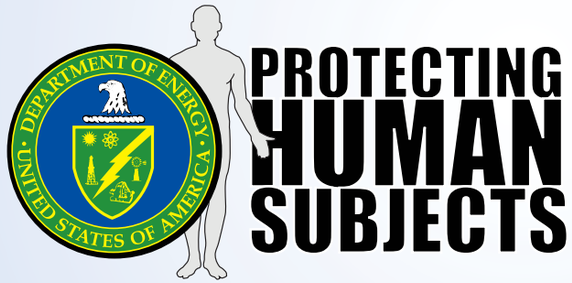
DOE Human Subjects Research Projects Database
http://hsrd.orau.gov/
Oak Ridge Associated Universities (ORAU)
Phone: 865-241-3744
E-mail: Don.Watkins@orise.orau.gov

Department of Health and Human Services
Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852
Phone: 240-453-6900
Fax: 240-453-6909

Local Human Subjects Coordinator

ARE YOU CONDUCTING HUMAN SUBJECTS RESEARCH?

It's More Than You Might Think!



PROTECTING HUMAN SUBJECTS

ARE YOU CONDUCTING RESEARCH USING HUMAN SUBJECTS?

Legal requirements to protect human subjects apply to a much broader range of research than many investigators realize. In addition to covering traditional biomedical studies, legal obligations to protect human subjects also apply if your research involves any of these:

- Private information or general data (including surveys) that are identifiable to specific individuals
- Tissue, specimens, or bodily materials traceable to specific individuals
- Intervention or interaction with human subjects, or
- Use of humans to test devices, products or materials developed through research

Then federal laws govern your work and specific requirements must be met before your study can begin.

IF SO, YOU MUST…

Comply with federal regulations and U.S. Department of Energy (DOE) directives to protect human subjects.[1] These requirements apply if your research is conducted using DOE funding, facilities or property, or if your research includes as participants DOE employees or contractors or their identified information.

The Under Secretary for Science monitors implementation of 10 CFR 745 within the Department in accordance with policy established by the Secretary and DOE P 443.1A, and determines what constitutes Departmental-related human subject research in consultation with the National Nuclear Security Agency (NNSA), as appropriate.

As defined in 10 CFR 745 –
Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Human Subject means a living individual about whom an investigator (whether professional or student) conducting research obtains
(1) data through intervention or interaction with the individual, or
(2) identifiable private information.

For proprietary or classified projects, contact DOE or your local human subjects coordinator. These projects are not exempt from DOE Human Subjects regulations.

[1] Title 10, Code of Federal Regulations, Part 745, Federal Policy for the Protection of Human Subjects; Notices and Rules

Policy and Order on the Protection of Human Subjects (2007)

Order on Work for Others (Non-Department of Energy Funded Work) (2005)

For a full-text version of these orders and policy, see the DOE Human Subjects Research Program Website at: http://humansubjects.energy.gov

No human subjects research may be conducted with DOE funding, at DOE institutions, or by DOE personnel without both a Federal Wide Assurance (FWA, see http://www.hhs.gov/ohrp/assurances/assurances_index.html) and approval by the cognizant Institutional Review Board (IRB) in accordance with 10 CFR745.103.

WHAT IS THE ROLE OF THE INSTITUTIONAL REVIEW BOARD (IRB)?

The IRB at your institution must review and approve research if it involves human subjects. This process is designed to ensure that the investigators who conduct the research protect the rights and welfare of human subjects—for example, by minimizing risks, selecting subjects equitably, obtaining informed consent, and ensuring privacy and confidentiality.

IRB approval must precede initiation of any work involving human subjects. If the research continues, the IRB must review and approve the project at least once a year.

When changes occur in the procedures involving research with human subjects, the IRB must review and approve these changes.

If unexpected or adverse effects occur, including any harm, physical injury, or economic loss to research subjects, or improper disclosure of private information, or any other harmful or potentially harmful occurrences, IRB notification is required.

PROTECTING HUMAN SUBJECTS

WHAT IF YOUR INSTITUTION HAS NO IRB?

- Establish an IRB at your institution if the number of research projects involving human subjects justifies this step.
- Alternately, retain the services of an IRB at another institution that satisfies all federal and DOE requirements to review research involving human subjects at your institution.
- Obtain approval from DOE for the newly created or retained IRB.
- Submit a FWA application to OHRP, naming the newly formed or contracted IRB.

For more information on these options, contact the headquarters human subjects program manager listed in the **Who to Contact** panel.

Types of IRB Review

Full Board (Convened Review)—Review of proposed research at a convened meeting at which a valid quorum of IRB members is present. For the research to be approved, it must receive the approval of a majority of those members present.

Expedited Review—Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk* and for minor changes in previously approved research.

Exemption—Exemption from the requirement for IRB approval when it is determined that research does not involve human subjects as defined in 10 CFR 745 and/or the only involvement of human subjects is in one of the categories listed under 10 CFR 745 Sec. 101(b)(1)-(6). Human subjects regulations do not apply to exempt projects. Any research project involving human subjects thought to be exempt must be submitted to the IRB or other authority according to local procedures for determination of exempt status.

***Minimal Risk**—The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

WHAT IS INFORMED CONSENT?

The human subjects in your project must participate willingly, having been adequately informed about the research. If the human subjects in your project are part of a vulnerable population, such as prisoners or children, special protections are required. For more information on vulnerable populations, consult the DOE Human Subjects Protection Resource Book, or Institutional Review Board Guidebook published by the Office of Human Research Protection (OHRP) at the Department of Health and Human Services.

ESSENTIALS OF INFORMED CONSENT

Voluntary participation also means that subjects have enough information to give true informed consent. Essential information includes—

- **Purpose** of the research.
- **Benefits** of the research to society and, possibly, to the individual human subject.
- All **foreseeable risks or discomforts** to the subject. Note that these include not only physical injury, but also possible psychological, social, or economic harm, discomfort, or inconvenience.
- **Length of time** subject is expected to participate.
- **Person to contact** for answers to questions, or in the event of a research-related injury or emergency.
- **Statement that participation is voluntary** and that refusal to participate will not result in any penalty or any loss of benefits that the person is otherwise entitled to receive.
- Subjects' **right to withdraw** from the study at any time.

For **classified research**, the consent form must provide the name of the research sponsor, describe the nature of the research, and state that the research is classified.

Consent documents must be clearly written and understandable to subjects. The language must be nontechnical (comparable to the language in a newspaper or general circulation magazine), and scientific, technical, or medical terms must be plainly defined.

Informed consent, whether oral or written, may not include language that appears to waive subjects' legal rights or appears to release the investigator or anyone else from liability for negligence.

Federal policy has been altered to strengthen the conditions under which classified research is reported to research subjects. It is important to thoroughly review and understand the most current regulations before starting research.

TO LEARN MORE…

Please refer to:
The DOE Human Subjects Program website:
http://humansubjects.energy.gov/ which includes:

- The DOE Human Subjects Protection Resource Book
- Protecting Human Subjects newsletters
- Protecting Human Subjects poster
- Other relevant information

For additional guidance:

- OHRP's Institutional Review Board Guidebook
- OHRP Human Subjects Protections website: http://www.hhs.gov/ohrp/